Medication Management

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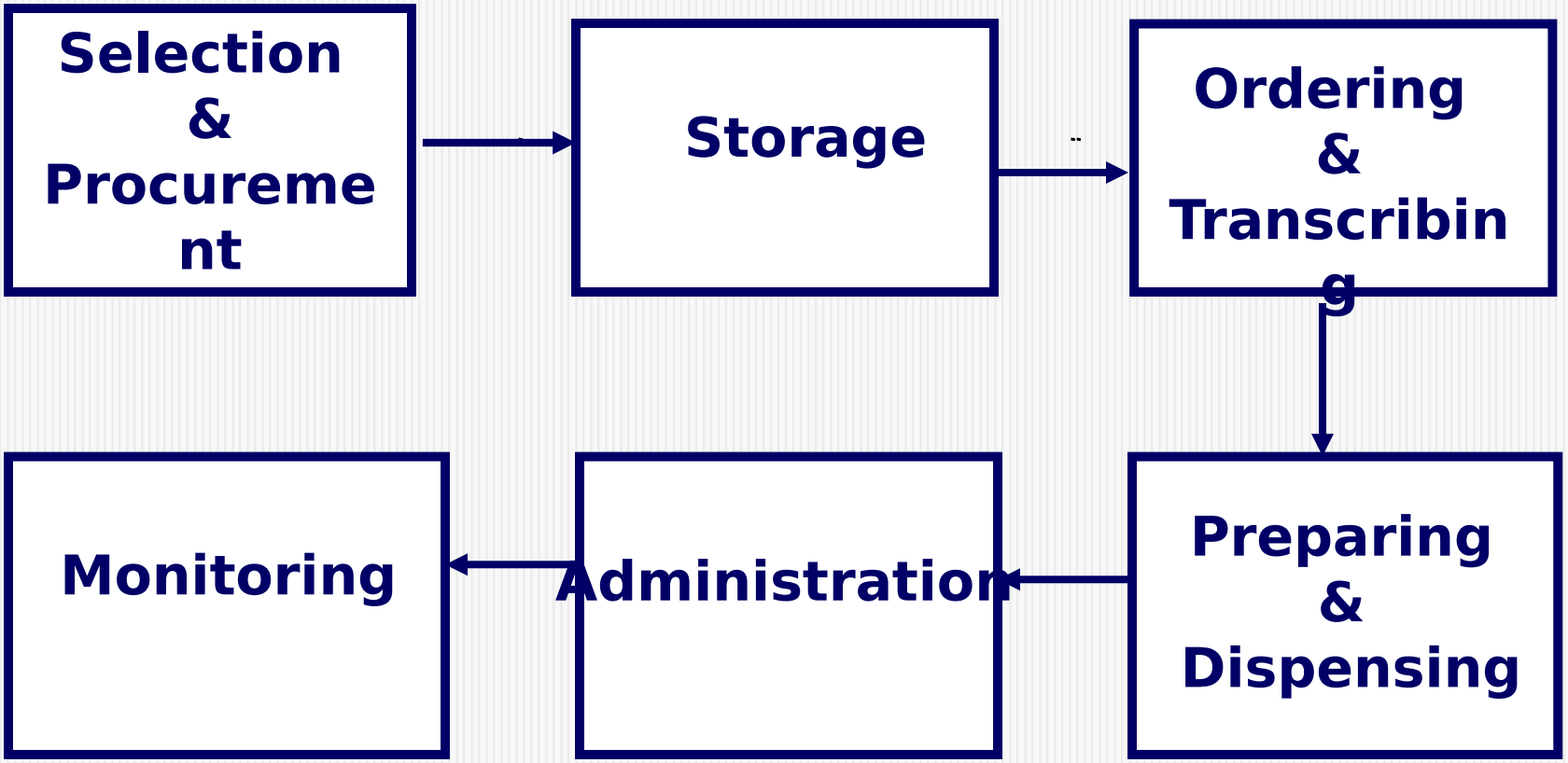
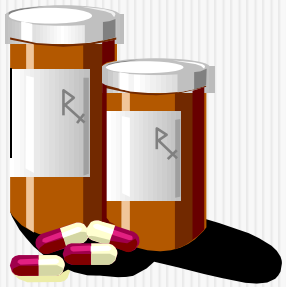
The Medication Management Process





The 6 Critical Processes

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Revised JCAHO Definition of a Medication

- Any product designated as a drug by FDA:
  - Vaccines, diagnostic and contrast agents
  - Prescription medications
    - Respiratory therapy treatments, TPN, sample medications, radioactive medications, blood derivatives, IV solutions, and others
  - Over-the-counter medications;
  - Herbal remedies, nutriceuticals, vitamins and health supplements

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Revised JCAHO Definition of a Medication

- Excludes:
  - Enteral nutrition solutions
  - Oxygen and medical/anesthetic gases

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MM.1.10
Patient-Specific Information

- Patient-specific information readily available
  - Written policy
  - Minimum information
  - Accessible when needed

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MM.2.10 Medications Available

- Applicable to AHC, HAP
- Challenging standard for HAP
- Based on criteria
  - Selected
  - Listed
  - Procured

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MM.2.20
Medication Storage

- Applicable to AHC, HAP
- Challenging standard for HAP and Army
  - EP # 3 – Secured medications
  - EP # 4 – Controlled substances
  - EP #6 – Segregation of sound-alike, look-alikes
  - EP #7 – Meds and chemicals used to prepare are labeled
  - EP #8 – Concentrations standardized and limited – NPSG #3b
  - EP #9 – Concentrated lytes managed – NPSG #3a

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MM.2.30
Emergency Medications

- Emergency medications/supplies available, controlled, secured
  - Leadership role
  - Unit-dose, age-specific, ready to administer
  - Stored in:
    - Sealed or locked containers
    - Locked room
    - Under constant supervision
  - Replacement process

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MM.2.40
Patient's Medications

- Process established for medications brought into the organization by patients/families
  - When applicable
  - Process for identification / visual inspection
  - Process to inform provider and patients if not permitted

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MM.3.10
Medication Ordering

- Applicable to AHC, HAP
- Challenging standard for HAP
- Only medications needed to treat the patient's condition are ordered
  - Documentation required
  - Various locations acceptable
    - Orders
    - Progress notes
    - Consultants reports
    - Nursing notes

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MM.3.20
Medication Ordered

- Applicable to AHC, HAP
- Challenging standard for HAP and Army
- Written clearly
- Transcribed accurately
- Organization should take steps to reduce the potential for error or misinterpretation

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MM.4.10
Medication Preparation

- Applicable to AHC, HAP
- Challenging standard for HAP and Army
- Prescriptions or medication orders are reviewed for appropriateness
  - Drug, does, frequency and route
  - Therapeutic duplication
  - Allergies / sensitivities
  - Interactions
  - Contraindications
  - Criteria for use
  - Medication related issues

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MM.4.20
Medication Preparation

- Applicable to AHC, HAP
- Challenging standard for HAP
- Medications are prepared safely
  - On-site pharmacy compounding
  - All staff use safety materials and equipment while in preparing meds
  - Techniques used to assure accuracy
  - Techniques to avoid contamination

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MM.4.40
Appropriate Dispensing

- Applicable to AHC, HAP
- Challenging standard for HAP and Army
- Medications dispensed safely
  - Quantities dispensed minimize diversion
  - Law, regs, licensure, standards of practice are followed
  - Medications dispensed timely
  - Dispensing in most ready-to-administer forms
  - Same dose packaging or staff education on differing systems

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MM.4.50
Pharmacy Closed

- System for safely providing medications when pharmacy closed
- Role of non-pharmacist allowed by law and regulation
  - Limited access
  - Trained, designated prescribers/nurses
  - Quality control procedures
  - Qualified pharmacist available
- Process evaluated on ongoing basis

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MM.4.60
No Pharmacy

- Applicable to AHC only
- Organization has a process for obtaining medications
  - If organization routinely administers medications
  - No pharmacy operated

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MM.4.70
Recall Process

- Medications retrieved when recalled or discontinued by FDA, manufacturer
  - Retrieval process
  - Appropriate handling
  - Individuals involved in ordering, dispensing and/or administering are notified
  - Patients are notified

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MM.4.80
Returned Medications

- Challenging standard for Army
- Medications returned to pharmacy are managed appropriately
  - Process in place for unused, expired or returned medications
  - Pharmacy control prevents diversion
  - Process for destruction

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MM.5.10
Administering Medications

- Medications safety and accurately administered
  - Guidelines for notification of adverse drug reactions/medication errors
  - Verification process for administration

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MM.5.20 Self-Administered Medications

- Self-administered are safely and accurately administered
  - Procedures guide practice
  - Training and appropriate information for non-staff members
  - Competence determined

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MM.6.10
Monitoring the Effects on Patients

- Effects of medications are monitored
  - Patient's response according to clinical needs
  - Monitoring includes
    - Gathering patient's own perceptions
    - Referring to information from medical record
  - Process for monitoring the first dose (s) of medication new to patient

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MM.6.20
Monitoring Medications

- Organization responds appropriately to actual or potential adverse drug events and medication errors
  - Process in place
  - Appropriate action taken
  - Organization complies with internal and external reporting requirements

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MM.7.10
High-risk, High-alert Medications

- Organization develops processes for managing high-risk or high-alert medications
  - High-risk and high-alert medications identified
  - Processes in place

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MM.7.40
Investigational Medications

- Investigational medications safety controlled and administered
- Procedures in place
  - Written process
  - Medication protocols
  - Pharmacy involvement
  - Review all investigations medications to evaluate safety (see RI.2.180)

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MM.8.10
Evaluation

- The organization evaluates its medication management system
  - Risk points and areas to improve
  - Routine evaluate of literature
  - Review of internally generated reports (PI.2.10 and PI.2.20)

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Medication Management Systems Tracer

- Objectives
  - Evaluate continuity of medication management processes
  - Complete high level analysis of medication management system
  - Identify potential medication management vulnerabilities
  - Assess compliance with standards

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Medication Management

- Sub-processes for this PFA include
  - Selection and procurement
  - Storage
  - Ordering and prescribing
  - Preparing and dispensing
  - Administration
  - Monitoring

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Medication Management Systems Tracer Guidelines

- Group Discussion
  - Review of medication management processes
    - Risk points (six processes)
    - Immediate or proximal causes for any issue
    - Systems issues
    - Potential solutions
  - Critical thinking about medication processes
  - Potential vulnerabilities
  - ID issues requiring further exploration
  - Review of NPSGs related to medication management

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Medication Management System Tracer Example

- Select a patient record of a complex patient
- For each patient review the patient charts and select three high risk drugs per patient to review.
  - In selecting high risk drugs consider:
    - Medication for pain management
    - Antibiotics
    - Blood thinner (e.g. coumadin)
    - Other high risk medications (e.g. insulin)

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Medication Management Systems Tracer Example

- Compare record information:
  - MAR (5 “R’s)
  - Notes
    - Monitoring effects
    - Change in condition
  - Lab values
- Interview Staff
  - Direct care providers
  - Managers

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Medication Management Systems Tracer Example

- Pharmacy profile
- Pharmacy review for appropriateness
- Interview Pharmacist

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USP-NF Chapter 797 Pharmaceutical Compounding – Sterile Preparations

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From Recommendation to Regulation

- Outbreak of nosocomial infections during 1970's
- National Coordinating Committee on Large Volume Parenterals (NCCLVP) formed
- Guidelines for preparation, labeling, administration and quality assurance of IV products and therapy developed

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Other Organizations Involved

- Organizations involved later included
  - United States Pharmacopeia (USP)
  - American Society of Health-System Pharmacists (ASHP)
  - National Association of Board of Pharmacy (NABP)
- Developed and issued practice standards for pharmacists and technicians

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The Problem……

- Standards consisted of recommendations and guidelines
- Not enforceable by regulatory agencies
- National survey by ASHP revealed few pharmacies controlled compounding areas
- Many pharmacists not performing:
  - Quality checks
  - End product sterility testing
  - Process validation

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The Result……

- In adequate protection of patients from harm or death resulting from compounding
- Multiple injuries and deaths over the last three decades
- Focus of lay press and FDA

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Purpose of USP Chapter

- Develop standards in sterile compounding
- Do the “right thing” for patients
- Avoid FDA from taking control of pharmacy compounding
- Improve quality assurance

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Scope of Chapter 797

- Applies to:
  - Health care institutions
  - Pharmacies
  - Physicians practice facilities
  - Other facilities in which compounded sterile preparations are:
    - Prepared
    - Stored
    - Dispensed

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Facilities Impacted

- Sterile products are prepared according to manufacturer's labeling and where manipulations are performed during compounding
- Products are compounded using devices or ingredients which are not sterile to prepare product which must be sterilized prior to use
- Products may be biologicals, diagnostics, drugs, nutrients or radiopharmaceuticals

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Definition of Compounding

- Does not mean:
  - Products that are prepared for immediate use
- Does mean:
  - Preparation and longer-term storage of that product

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Questions?

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